

### **REMARKS/ARGUMENTS**

Regarding the Final Office Action dated 03/17/2006, Applicant respectfully requests that claims 1, 3, 4, 7, 10, 11 and 21 be amended and that claims 2, 5, 6, 13-15 and 18-20 be canceled, as indicated above in the Listing of Claims, and that the following remarks and arguments be considered.

Applicant asserts that the claims as amended comply with 37 C.F.R. §1.116 such that they are fully supported in the application as originally filed and contain no new matter, and respectfully request reconsideration for the following reasons.

#### **I. Claim Rejections under 35 USC §§102,103 – rejection of Claims 1-20**

Claims 1-20 remain rejected under 35 USC §102(b) as anticipated by or, in the alternative, under 35 USC §103(a) as obvious over Depel et al., U.S. Patent No. 4,582,058 (“Depel”).

Applicant has amended claims 1, 3, 4, 7, 10, and 11, and canceled claims 2, 5, 6, 13-15 and 18-20 to better define the invention over Depel.

Specifically regarding the first valve, the Examiner asserts that Depel teaches a tracheotomy valve unit in which the first valve comprises “a seating ring 8, a thin, flexible diaphragm 7 biased against the seating ring, thereby making positive closure contact therewith, and a rivet 9 for connecting the diaphragm to the seating ring, the rivet having a length to bias the diaphragm against the seating ring.” Applicant cannot agree, in light of the current amendments.

The terminology given by the Examiner to the corresponding elements of Depel’s valve is inaccurate. The element asserted by the Examiner to be a “flexible diaphragm 7” is neither flexible nor a diaphragm, as required by amended claim 1, but rather a hard, plastic valve disc 7 with a plurality of openings 7b therein, and the sealing ring 8 of Depel does not extend from the support around the outer periphery of the air ports, as the seating ring 36 of the present invention does. (See col. 3, lines 21-25 and col. 4, lines 14-30 of Depel, and compare disc 7 of FIG. 4 of Depel to the diaphragm 18 of FIG. 3 of present application). Also, what the Examiner refers to as a “rivet 9 for connecting the diaphragm to the seating ring” is in fact a “spring 9” which holds

“the disc 7 against the spider 15 and the flexible valve unit 6.” (See col. 4, lines 55-60 of Depel). The valve unit of the present invention includes no spring, and no spider.

Thus, contrary to the Examiner’s assertions, the valve unit of Depel does not include a thin, flexible diaphragm biased against the seating ring and making positive closure contact therewith. Further, the spring/ ‘rivet’ 9 of Depel does not connect the disc/diaphragm 7 to the sealing/seating ring 8, as asserted by the Examiner and required in amended claim 1. Rather, the spring 9 of Depel “engages the disc 7 to predeterminely position and bias the disc 7 *away from* the sealing ring 8.” (See col. 4, lines 51-54 of Depel; Emphasis added).

Amended claim 1 includes other structural elements to distinguish the invention over Depel. Specifically, the valve unit inlet at the second end comprises a support having air ports and disk-shaped member defining a hole therethrough for the rivet to fit into, and a seating ring extending inward from the support around the outer periphery of the air ports. These amendments are supported by the Specification at pages 5-7, paragraphs 25-30. Additionally, the rivet portion of the first valve must be adapted to sealingly fit into the hole defined by the disk-shaped member. The valve unit of Depel does not disclose a disk-shaped member defining a hole into which the spring 9 sealingly fits into, and as such does not anticipate claim 1, as amended. Stated another way, the spring 9 of Depel does not anticipate the rivet 20 of the present invention because they are simply non-analogous elements.

Indeed, it is readily apparent when comparing FIG. 4 of Depel to FIG. 3 of the present application, that the first valve of Depel includes a complicated array of elements that are not present, and are simply not required, in the present invention. Even if Depel can be said to disclose the seating ring, the flexible diaphragm and the rivet of the present invention, there are so many more elements required in the valve unit of Depel for its proper functioning that the seating ring 8 (seating ring), the hard disc 7 (flexible diaphragm) and the spring 9 (rivet) alone, could not result in a functioning valve unit.

Regarding the second valve of amended claim 1, the Examiner asserts that col. 5, lines 38-45 of Depel teaches that “the blow-out/second valve may be predeterminely tuned, i.e., the valve may be set at a certain pressure at which to open and close, such that it would have been obvious, if not inherent, to one of ordinary skill in the art to provide the second valve opening

and closing at a certain pressure based on the intended use of the valve.” Applicant asserts that claim 1, as currently amended, distinguishes the second valve over Depel.

Specifically, the second valve of amended claim 1 is “located in an axial bore hole of the rivet and operable to open during pressures associated with speaking.” Depel does not disclose a second valve located in an axial bore hole of the rivet, much less a second valve that opens during pressures associated with speaking, and so does not anticipate claim 1. Further, column 5, lines 38-45 of Depel states that the blow-out or relief valve “may be predeterminedly tuned and sized to open and release the increased air pressure within the valve assembly...” (Emphasis added). This increased air pressure is always attributed in Depel to increased or high air pressure within the valve assembly, such as due to a cough or the like, which is much greater than pressures generated during speaking. The Depel valve is designed to prevent severe discomfort associated with increased intrathoracic pressure, and is intended to avoid high intrathoracic pressures from causing the valve unit to pop off of the tracheotomy tube and shoot across the room upon coughing. The Depel valve is not able to be tuned to allow air exit during speech. In addition, the Abstract of Depel discloses that the blow-out/second valve is in the *closed* position during speaking: “The valve assembly includes a separate external relief valve which is closed during normal vegetative breathing and speaking” (Emphasis added). See also Column 7, line 29 to Column 8, line 5 of Depel.

In contrast, claim 1, as amended, discloses that the second valve is open during pressures associated with speaking. These are typically very low pressures and, as specifically indicated in claim 1, as amended, the second valve “begins to open to permit airflow from the tube through the valve unit and out the valve unit when the intrathoracic pressure during expiration is greater than about 3 cm of water, allows increasing airflow through it as the intrathoracic pressure during expiration increases, is fully open and allows maximum airflow therethrough when the intrathoracic pressure reaches about 12 cm of water, and blocks such airflow when the intrathoracic pressure during expiration is less than about 3 cm of water.” Support for this amendment is found at page 12, paragraph 45 of the Specification (See also page 9, paragraph 36.) Thus, the opening of the second valve of the present invention at low pressures is in direct contrast with the blow-out valve of Depel, which remains closed, until uncomfortably increased or high pressures associated with coughing occur. One of ordinary skill in the art will understand

that pressures associated with coughing are typically about 100 cm of water or greater, or much higher than 3-12 cm of water.

A claim is anticipated under 35 USC §102(b) “only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” See *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d (BNA) 1051, 1053 (Fed. Cir. 1987). As described in detail above, Depel does not disclose each and every element of the first valve as set forth in currently amended claim 1, such that Depel does not anticipate claim 1. Also, because Depel does not disclose a second valve located in an axial bore hole of the rivet, or a second valve that opens during pressures associated with speaking (and in fact teaches that it remains closed during speaking), Applicant asserts that Depel does not disclose, either expressly or inherently, each and every element of the second valve as set forth in claim 1. Applicant thus respectfully asserts that claims 1-20, as amended, are not anticipated by Depel under 35 USC §102, and respectfully requests that this rejection be withdrawn and the claims, as amended, be reconsidered and allowed.

To show a *prima facie* case of obviousness, all of the claim limitations must be taught or suggested by the reference (or references, when combined). See *In Re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). As noted above, Depel actually teaches away from a second valve being open during pressures associated with speaking. As noted above, the Abstract of Depel discloses that the blow-out/second valve is in the *closed* position during speaking: “The valve assembly includes a separate external relief valve which is closed during normal vegetative breathing and speaking” (Emphasis added). See also Column 7, line 29 to Column 8, line 5 of Depel. Thus, since Depel explicitly states that the relief or blow-out/second valve is closed during speaking, and only opens under substantially increased air pressure, such as due to a cough or the like, it cannot be maintained that Depel teaches or suggests to those of ordinary skill in the art the utility of having a blow-out/second valve which can be open during pressures associated with speaking. Thus, Applicant respectfully requests that the rejection of claims 1-20 under 35 USC 103(a) be withdrawn and the claims, as amended, be reconsidered and allowed.

## **II. Claim Rejections under 35 USC §§103 – rejection of Claims 21-25**

Claims 21-25 are rejected under 35 USC §103(a) as being obvious over Lurie, U.S. Patent No. 6,604,523 (“Lurie”).

To show a *prima facie* case of obviousness, all of the claim limitations must be taught or suggested by the reference (or references, when combined). See *In Re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Further, “a proper analysis under §103 requires consideration of whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process.” See *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). Applicant has amended claim 21 to better define the invention over Lurie.

Applicant asserts that Lurie does not teach or suggest a disk-shaped member defining a hole into which the rivet sealingly fits into, as required in currently amended claim 21. The Examiner asserts that Lurie, at Figure 16A and col. 21, lines 1-5 and 15-30, teaches a tracheotomy valve unit in which the first valve comprises “a seating ring (the cylindrical shape region 144 where the diaphragm is resting), a thin, flexible diaphragm (148) biased against the seating ring, thereby making positive closure contact therewith, and a rivet (150) having a length to bias the diaphragm against the seating ring.”

Amended claim 21 includes structural elements that distinguish the invention over Lurie, including a support having air ports and a disk-shaped member defining a hole therethrough for the rivet to fit into. The ‘rivet’ 150 of Lurie (named therein a fenestrated mount) does not teach or suggest a disk-shaped member defining a hole into which the rivet/fenestrated mount 150 sealingly fits into. Further, the fenestrated mount 150 of Lurie does not teach or suggest biasing the diaphragm 148 against the seating ring (i.e. a “cylindrical housing” in Lurie). Indeed, the fenestrated mount 150 of Lurie and the rivet 36 of the present invention are simply non-analogous elements.

Regarding the functional pressure ranges attributed to Lurie by the Examiner, Applicant asserts that the valve unit of Lurie is from non-analogous art and as such cannot be compared in a meaningful manner to the valve unit of the present invention. Lurie relates to devices and methods for increasing cardiopulmonary circulation in critically ill patients with severe low blood pressure. The present invention relates to a pressure release valve unit that improves

comfort during voluntary breathing and speaking for conscious patients who require a tracheotomy valve. While the apparatus of Lurie can be physically connected to a tracheotomy tube, Lurie provides no suggestion or motivation of the desirability to combine its life-saving apparatus with a tracheotomy tube that enables speech. Nowhere does Lurie suggest the desirability of using its life-saving apparatus to enable speech in the patient during cardiopulmonary resuscitation. Applicant respectfully asserts that the Examiner is using hindsight, attributing elements and their functions to Lurie only after the present invention has claimed those elements and functions, which is impermissible.

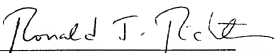
In light of the above, it cannot be maintained that the present invention is obvious over Lurie. Thus, Applicant respectfully requests that the rejection of claims 21-25 under 35 USC 103(a) be withdrawn and that claims 21-25, as amended, be reconsidered and allowed.

### **CONCLUSION**

Applicant has addressed each point raised in the Final Office Action dated 03/17/2006 in the present Response, and respectfully requests reconsideration of the present application in view of the foregoing Request for Continued Examination and the amendments and remarks, that the rejection of claims 1-25 be withdrawn, and that remaining claims 1, 3, 4, 7-12, 16, 17 and 21-25 be duly allowed.

The Examiner is invited to contact the undersigned directly with any questions or remaining issues regarding the pending claims.

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